#### REMARKS

Claims 24, 25, 28-35 and 44 are pending in this application. Claims 24, 25 and 29, the specification and the drawings are amended. Claim 44 is added. The amendments and added claim introduce no new matter. Support for the amendments to the claims can be found in, for example, the claims, specification and drawings, as originally filed. Claims 26, 27 and 36-43 are canceled without prejudice to, or disclaimer of, the subject matter recited in these claims. Reconsideration of the application based on the above amendments and the following remarks is respectfully requested.

## I. <u>Certified Copy of Priority Document</u>

The Office Action indicates that a certified copy of the foreign priority document, Australian Application No. 2003905455, filed October 3, 2003, has not been received by the Patent Office. Upon review of the Patent Office's electronic records, however, a certified copy of Australian Application No. 2003905455 was received by the Patent Office on March 30, 2006. As such, the Applicant respectfully requests acknowledgement by the Patent Office, in writing, that the certified copy has been received and that the Applicant's claim for priority has been perfected.

#### **II.** Objection to the Drawings

In response to the objection to the drawings, new drawing sheets with replacements for FIGS. 1-29 are being submitted simultaneously with this amendment. The Applicant respectfully submits that these drawing sheets do not constitute new matter. Specifically, the elements shown in FIGS. 1-29 either illustrate elements previously identified in FIGS. 1-29, as filed, or present elements described in the specification, as filed.

In accordance with the amendments to the drawings, the specification has also been amended. The amendments to the specification merely clarify elements depicted in FIGS. 4, 5, 20 and 22 that are described elsewhere in the specification as filed. Moreover, these amendments are clearly supported by the drawings as filed, as would be understood by one of ordinary skill in the art. The Examiner's approval of the replacement drawing sheets for FIGS. 1-29 and entry of the amendments to the specification are respectfully requested.

# III. Formal Rejections under 35 U.S.C. § 112

Claims 25-29 and 41-43 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Claim 25 is amended to obviate the rejection of this claim. The cancellation of claims 26 and 41 renders the rejection of these claims, and the claims depending therefrom, moot. Withdrawal of the § 112 rejection is respectfully requested.

## IV. Prior Art Rejections under 35 U.S.C. § 103

Claims 36-39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,332,774 to Chikami. Claims 24, 26-35 and 41-43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chikami in view of U.S. Patent No. 4,026,023 to Fisher. Claim 25 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Chikami in view of Fisher and in further view of U.S. Patent No. 5,002,485 to Aagesen. The Applicant respectfully requests reconsideration of these rejections.

## A. <u>Independent Claim 24</u>

Claim 24 was rejected under 35 U.S.C. § 103(a) as being obvious over Chikami in view of Fisher. Without conceding the propriety of this rejection, and solely to advance prosecution of this application, claim 24 is amended to recite:

"the arch wire extends from one side posterior portion of the base to the other side posterior portion of the base for contact with outer surfaces of the set of teeth along an outside of the arch of teeth, and the arch wire exits the posterior portions on each side of the base at locations spaced from the arch of teeth, the arch wire extending from the posterior portions indirectly, generally rearwardly and outwardly relative to the wearer when in situ, to the set of teeth in bent portions of wire on each side of the base so as to allow flexure of the bent portions of wire between the base and the set of teeth, thereby promoting limited movement of the arch wire relative to the base when the dental appliance is in use."

Neither Chikami nor Fisher, nor any prior art of record, individually or combination, disclose, or suggest, this combination of features.

With reference to FIG. 1, Chikami discloses a retainer wire 50 composed of a holding portion 51 to fit on the front teeth and a metal wire 52 comprising a spring portion 52a and a supporting portion 52b fixed to the holding portion 51 (col. 4, ll. 1-11). Chikami teaches that the retainer wire 50 has greater extractive strength over conventional retainer wires because the metal wire 52 is embedded in the holding portion 51 (col. 4, ll. 12-31). With reference to FIGS. 6 and 7, Chikami describes a conventional retainer device comprising a base part 1 with a retainer wire 10 whose end portions are both fixed to the base part 1 to form a loop to enclose a plurality of teeth (*See* FIG. 7, col. 1, ll. 18-24). Chikami, however, does not disclose the arch wire exits the posterior portions on each side of the base at locations spaced from the arch of teeth, the arch wire extending from the posterior portions indirectly, generally rearwardly and outwardly relative to the wearer when in situ, to the set of teeth in bent portions of wire on each side of the base so as to allow flexure of the bent portions of wire between the base and the set of teeth, as recited in claim 24.

As clearly shown in FIGS. 1 and 7 of Chikami, the wire is in a loop and closely looped around the teeth in a holding pattern. The wire is closely and rigidly linked to the teeth. In contrast, as illustrated in FIG. 1, the present invention comprises an arch wire 14 disposed on the base 12 via expansion mechanism 40 and separated from the inner surface of the teeth by the bent portions in the arch wire (paragraph [0055]). One effect provided by this configuration is reduced rigidity surrounding the teeth 17 as is often the case with conventional dental appliances (paragraph [0055]). The Chikami device is an example of a conventional device.

Due to its restrictive configuration, the Chikami retainer is used for retention and not for development of the jaw structure, as would be understood by one of ordinary skill in the art. In this regard, Chikami's device applies a significant extractive force of each metal wire from the holding portion of at least 9.0 kg (Claim 7). Using a rigid design, the Chikami wire does not bend or flex but rather grasps the teeth for retention. The wire is rigidly held together to the acrylic and teeth and has very little give, hence drawing inwards the architecture or making things smaller acting as a clamp. In the event of a growth pattern or relapse because, for example, the patient did not wear the retainer for some time there would be considerable difficulty as the restrictive design Chikami only accommodates retention.

In contrast, the dental appliance of the present invention is of the Splint Orthodontic Myofunctional Appliance (SOMA) type. While the present invention can be used for retentive purposes via control of the acrylic base 21 and expansion mechanism 40, it also serves to guide teeth via the arch wire 14 during expansion to prevent tipping. In this regard, the flexible wire 14 applies a small, controlled force on the teeth as a result of the long length of the wire, bends made in the wire and the location at which the wire 14 exits the acrylic base 12 to reach the teeth.

Differences in applied force to the teeth have a significant impact on the efficacy of orthodontic treatment. Large heavy forces, such as those that would result from the Chikami device, applied to the teeth have a reduced effective treatment potential, while small light forces have a much higher treatment potential. The difference in treatment potential stems from their influence on the palatal sutures and cranial respiratory impulse. This affects the capacity for bone to grow at specific suture joints in the upper palate. Large forces restrict bone growth in the upper palate, thus restricting expansion of the upper palate. However, small forces do not restrict bone growth in the upper palate suture, thus allowing for more rapid expansion of the upper palate.

Moreover, the configuration of the appliance recited in claim 24 is a closed circuit, as would be understood by one of ordinary skill in the art. A closed circuit permits modulation of a neurological feedback response improving the efficacy of the dental treatment by increasing bone growth along the maxillary suture and improving appositional bone growth. The claimed labial arch wire design incorporates a full closed circuit. This allows teeth to be in the same vertical direction while unfolding the palate with simultaneous suture decompression due to positioning of jaws from the myofunctional perspective.

In contrast, the Chikami device is not a closed circuit. In fact, even if a screw mechanism were to be placed into the Chikami appliance and used for palatal expansion, the treatment process would not be as effective as the claimed invention at least because Chikami's rigid holding of the wire would restrict bone growth in the upper palate sutures, thereby restricting the rate of palatal expansion and potentially causing tipping of the teeth.

Fisher does not cure the deficiencies of Chikami. With reference to FIG. 2, Fisher discloses orthodontic appliance 22 including a plate 20 with five T-shaped closed flap springs 10A-E, an archwire 30, expansion screw 32 and clasps 34A and 34B (col. 3, 1l. 26-36).

However, Fisher also fails to disclose, or suggest, the arch wire exits the posterior portions on each side of the base <u>at locations spaced from the arch of teeth</u>, the arch wire extending from the posterior portions indirectly, generally rearwardly and outwardly relative to the wearer when in situ, to the set of teeth <u>in bent portions of wire on each side of the base so as to allow flexure of the bent portions of wire between the base and the set of teeth, as recited in claim 24.</u>

In Fisher, the closed flap springs 10A-E engage and direct movement of the teeth while the clasps 34A and 34B hold the teeth (*See* FIG. 2; col. 3, ll. 37-61). This design, however, suffers from the same drawbacks as discussed above with respect to Chikami, namely, clasps 34A and 34B rigidly lock the teeth into the orthodontic appliance and serve as a primary source of retention for the appliance and as disclosed in the Background portion of the Applicant's disclosure (*See* paragraphs [0002] and [0003]). In contrast, as illustrated in FIG. 1, the claimed appliance uses the acrylic to hug the teeth on the lingual side using undercuts of the existing teeth for primary retention. There is no acrylic in contact with any major portion of the palate except areas very close to the teeth. This provides space for the maxilla to unfold through which subsequent bone growth occurs at the mid maxillary and incisive sutures.

Further even if the Chikami wire were combined with the Fisher structure, the resulting combination would not have rendered obvious the combination of features recited in claim 24 at least because if a wire were placed on the Fisher appliance using the clasps 34A and 34B, the circuit would not be closed because clasps 34A and 34B are not a closed circuit themselves.

Finally, it is an object of the subject matter of the pending claims to improve breathing patterns and relieve improper facial muscle patterns. This has been achieved through the repositioning the jaw and natural release in the cranial base (particularly the spheno-basilar joint), relieving cranial strains. Subsequent orthodontic treatment may then follow with better and faster results. The novel integration of the combination of features recited in the pending claims reduces the need for tooth extractions and improves the rate of successful orthodontic movement, teinperoinandibular joint (TMJ) pain and joint pathology resolution including airway consideration improvements. In contrast, the rigid configurations of the Chikami and Fisher devices, and other conventional, orthodontic devices, cannot achieve the high degree of success in treating malocclusion. As such, Chikami and Fisher neither contemplate the advantages of the subject matter of the pending claims nor disclose the combination of features recited in claim 24.

Aagesen is not applied in a manner by the Office Action to overcome the above-

identified shortfalls in the application of Chikami and Fisher to the subject matter recited in

claim 24. In any regard, Aagesen discloses an appliance with a three-way screw mechanism and

an anterior platform, in which the lower teeth are locked into the plate using indentation in the

anterior platform to advance the lower jaw (See FIG. 2; col. 2, 11. 27-59). In Aagesen, the

primary retention mechanism is also rigid. As such, Aagesen does not cure the deficiencies of

Chikami and Fisher.

В. **Dependent Claim 44** 

Added claim 44 recites "at each side posterior portion the arch wire extends within the

base to the expansion screw so as to form a closed circuit." For at least the reasons discussed

above, the applied references, individually or in combination, do not disclose, or suggest, this

combination of features.

V. Conclusion

For the foregoing reasons, further examination of this application is respectfully

requested. The Examiner is invited, after consideration of this response, to contact the

undersigned to discuss any issue which would expedite allowance of this application.

The Office is authorized to charge any underpayment or credit any overpayment to

Deposit Account No. 11-0600.

Respectfully submitted,

Dated: December 30, 2008

By: /Christopher J. Wheeler/

Christopher J. Wheeler

Reg. No. 60,738

KENYON & KENYON LLP

1500 K Street, N.W.

Washington, D.C. 20005

202-220-4200 (phone)

202-220-4201 (facsimile)

-12-